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## Statement on Suitability for use under Food Contact Regulations

for

### ELASTOSIL® VARIO 40

#### 1. Europe:

Due to lack of specific European legislation on Silicones, these materials are subject to the Framework Regulation (EC) No. 1935/2004 and national provisions (Article 6). Provided appropriate processing, **ELASTOSIL® VARIO 40** and its catalyst batches **ELASTOSIL® KAT VARIO** or **ELASTOSIL® KAT VARIO-F** are suitable for the manufacture of food contact materials and articles under article 3 of the before mentioned Regulation. Compliance with the requirements of Regulation (EC) No.1935/2004 for the food contact material or article concerning any limitations in particular max. use limits or limits on migration or extraction, the effect on taste and smell of the food and the suitability of the article for the specific use must be ensured by the producer of the food contact material or article as it is placed on the market.

#### 2. Germany: Compliance with the Recommendations of the BfR:

The ingredients of **ELASTOSIL® VARIO 40** and its catalyst batches **ELASTOSIL® KAT VARIO** or **ELASTOSIL® KAT VARIO-F** are in compliance with the positive lists of the Recommendation XV. Silicones of the BfR.

Limitations: Extractable substances and volatiles may not exceed 0.5%.

#### 3. France:

The ingredients of **ELASTOSIL® VARIO 40** and its catalyst batches **ELASTOSIL® KAT VARIO** or **ELASTOSIL® KAT VARIO-F** are in compliance with the Arrêté du 25 novembre 1992.

Limitations: Total migration may not exceed 60 mg/kg food or food simulant, respectively, and volatiles are limited to 0.5%.

#### 4. USA: Compliance with FDA 21 CFR:

The ingredients of **ELASTOSIL® VARIO 40** and its catalyst batches **ELASTOSIL® KAT VARIO** or **ELASTOSIL® KAT VARIO-F** are in compliance with 21 CFR §177.2600 Rubber articles intended for repeated use and §175.300 Resinous and Polymeric Coatings.

Limitations: §177.2600 Rubber articles intended for repeated use:

Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total

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extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

Limitations: §175.300 Resinous and Polymeric Coatings:  
The final food contact coating in its cured state has to meet the extractive limitations under 175.300 (c).

Please note that due to its high platinum content, **ELASTOSIL® KAT VARIO-F** is limited to a maximum use level of 10%.

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility to meet extraction or migration limits subject to the a.m. regulations resides with the manufacturer of the finished product.

Wacker-Chemie AG

Burghausen, October 29, 2012

A handwritten signature in black ink, appearing to read "Burger".

Dr. C. Burger  
GB-S-IMS Manager Product Stewardship 1

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